# EXHIBIT 136

MYLAN

DATE: January 23, 2008

TO: File

FROM: Rebecca Pinnell RLP
Petecia Streater

SUBJECT: Final Corrective Action Memo – Audit XA-06-010

This audit is considered closed as the regulatory status of Actavis Totowa, LLC was identified and provided to Executive Management. Supporting documentation is located in the Audit file.

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# AUDIT REPORT COVER SHEET

**Audit Number:** XA-06-010

**Date(s) of Audit:** November 08-09, 2006

**Auditor(s):** Rebecca Pinnell
Petecia Streater

**Facility:** Actavis Totowa, LLC

**Audit Type:** cGMP Audit

**Product or Service Provided:** Digoxin Tablets, 0.125 and 0.25 mg

**Report Issue Date:** December 04, 2006

**Report Distribution:** Patricia Latzo, Senior Vice President of Quality, Mylan Pharmaceuticals Inc.

Michael Adams, Executive Director of Quality Assurance Compliance, Mylan Pharmaceuticals Inc.

Written By:

RPinnell
Rebecca Pinnell
Senior Quality Compliance Auditor, Quality Assurance

12/04/06
Date

Petecia Streater
Quality Compliance Auditor, Quality Assurance

12/04/06
Date

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Date: December 04, 2006

Audit #: XA-06-010

Auditor(s): Rebecca Pinnell, Petecia Streater

Facility: Actavis Totowa, LLC

Audit Type: Compliance History and Facility Report

Product or Service Provided: Digoxin Tablets, 0.125 and 0.25 mg

**SUMMARY:**

An audit of the regulatory compliance status of Actavis Totowa, LLC, 101 East Main Street, Little Falls, New Jersey, was conducted November 08-09, 2006. The auditors representing Mylan Pharmaceuticals, Inc. (MPI) were Rebecca Pinnell, Senior Quality Compliance Auditor, and Petecia Streater, Quality Compliance Auditor. Actavis Totowa, LLC, formerly Amide Pharmaceuticals, Inc., manufactures Digoxin tablets, 0.125 and 0.25 mg, for Mylan Pharmaceuticals Inc. (MPI), which are marketed as Digitek®.

Currently, there is a Supply and Distribution Agreement between Mylan Laboratories, Inc., Bertek Pharmaceuticals Inc., and Amide Pharmaceuticals, Inc. There is no Quality Agreement in place with Actavis Totowa, LLC.

The auditing team was received by Dan Bitler, Quality Assurance Director. The site visit included a tour of the facilities followed by a review of regulatory documents and procedures relating to their compliance history. Also representing Actavis Totowa, LLC during portions of the audit was Jasmine Shaw, Vice President of Regulatory Affairs.

**OVERVIEW:**

Compliance History

As of 06/10/02, Amide Pharmaceuticals
, Inc. was released from a Consent Decree that was initiated on 03/25/92.

Actavis Totowa, LLC received a warning letter on August 15, 2006 regarding the complaint system and failure to submit 15 day reports. This included specific references to Digoxin Tablets. The warning Letter also addressed the manufacture of drug products without approved applications. During the audit we were able to review the response to the Warning Letter, additional communication with the FDA regarding complaints, and the summary of Digoxin complaints submitted to the FDA. Copies of these documents were requested; however, they were not provided during the audit. Jasmine Shah, Vice President of Regulatory and Quality, indicated he would provide them later.

According to the Vice President of Regulatory and Quality, the FDA has accepted the response to the warning letter regarding complaints and considers that portion closed. In addition, the Vice President stated that the FDA reviewed the Complaint system during an audit in September and that the system was deemed acceptable. Actavis Totowa has been in communication with the FDA regarding the response for products manufactured without an approved application. The District Office has informed the Vice President of Regulatory and Quality that the response is acceptable and they have forwarded the written response to CDER. Actavis Totowa is waiting for an answer from CDER.

Actavis Totowa's laboratory and manufacturing facilities were inspected by the FDA in August 2006 and received 15 observations in the form of an FDA 483. We were provided documentation showing all corrective actions have been completed. We reviewed these documents specifically in response to the corrective actions provided to the FDA. This review did not include an in-depth systems audit. The Vice President of Regulatory and Quality believes the inspection will result in a Voluntary Action Indicated. Actavis Totowa has implemented a "Quality System Improvement Plan" (QSIP) in response to the inspection. QSIP is an ongoing quality process, where systems are reviewed and corrective actions are implemented. They have volunteered to provide the FDA a monthly update to include which systems were reviewed, the findings, and completed corrective actions. The Vice President of Regulatory and Quality said that these updates would only be provided to the FDA and only a note stating when the updates were submitted may be provided to clients. The "Supply and Distribution Agreement" states that Amide shall "provide to Bertek, within seventy-two (72) hours, copies of all relevant documents, including FDA Forms 482, 483 warning letters and other correspondence and notifications relating to products, as Bertek may reasonably request."

Actavis Totowa packaging was inspected by the FDA in September 2006 and received 3 observations. We requested the inspection and responses for the September audit prior to our visit. The documents were not made available for review and the Vice President of Regulatory and Quality indicated he would provide them later.

Actavis Totowa was inspected by the FDA in October 2006 and received no observations. According to the Quality Assurance Director, this inspection was in response to a Field Alert as a result of a product complaint in which a pharmacy mixed strengths of the product. The product was not Digoxin Tablets. Actavis Totowa has revised the label colors of the product strengths.

Amide Pharmaceuticals was acquired by Actavis in July 2005. Actavis also acquired Alpharma Pharmaceuticals in December in 2005. Amide Pharmaceuticals' manufacturing, packaging, and laboratories will remain autonomous while other systems will be harmonized. This acquisition will also provide for additional personnel and re-organization of upper management as well as renaming to Actavis Totowa, LLC. Current and in-process organizational charts were provided. A shortage of qualified personnel was apparent as key individuals were not readily available to discuss relevant issues due to ongoing meetings, interviews, and other scheduling conflicts.

Facilities

Actavis Totowa is currently leasing a 64,000 square foot facility where Digoxin tablets are being manufactured exclusively for MPI. In addition, they have remodeled a company owned warehouse into a 46,000 square foot facility which centralizes Packaging operations and R&D laboratories. Actavis Totowa has purchased and is in the process of expanding into a 115,000 square foot facility that will encompass manufacturing, Quality Control, and Shipping/Receiving operations. The leased manufacturing area was characterized by dated equipment. Also, the quality control laboratory area was congested. The warehouse for containers and closures was leaking water from the ventilation system and smelled of mildew upon entering.

In the new expansion facility, drop ceilings were being installed into the overhead rooms for the compression operations. The manufacturing rooms are lined with plastic sheeting and molding over the joints. Gaskets have been installed around lighting fixtures and outlets. Quality Assurance did not want to speculate on how effective cleaning would be conducted in these areas. It rained continuously on the first day of our tour and there were considerable amounts of water leaking through the ceilings of the new facility. The system is being constructed and qualified in two phases. We only toured Phase I which is currently undergoing qualification for ancillary systems. The Quality Assurance Director indicated that Actavis Totowa has been in communication with the FDA regarding the new facility. The FDA will walk-through the facility prior to the start of production.

Warehousing systems were relatively organized with appropriate segregation and color-coded labeling of released and non-released components, however we did observe white powder on the shelves and floor where some of the inactive raw materials were stored. During the tour, Quality Assurance indicated that the inventory process did not utilize the storage location numbers. However, upon review of the responses to the August 2006 inspection, it was found that these numbers are utilized and recorded on the raw material inventory cards.

Contractual Concerns

It was brought to the attention of the Vice President of Regulatory Affairs & Quality and the Director of Quality Assurance that the current "Supply and Distribution Agreement" requires Amide to submit relevant regulatory documents and correspondences to MPI. Despite these conversations with Amide Management and multiple requests for documentation before, during, and after the audit, copies of the following documents have yet to be provided:

- Actavis response to the August 2006 Warning Letter
- Summary of Digoxin complaints submitted to the FDA
- Correspondence with the FDA regarding complaints
- Periodic updates to the FDA regarding QSIP
- FDA 483 observations and responses to the September 2006 inspection